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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/955,444	09/17/2001	James M. Wilson	UPN-N2605	1285

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EXAMINER	
WHITEMAN, BRIAN A	
ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 03/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/955,444	Applicant(s) WILSON ET AL.	
	Examiner Brian Whiteman	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-22 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-22 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-7 and 10-18, drawn to a non-invasive method for obtaining pharmaceutically effective levels of a gene product in the bloodstream of a mammal, the method comprising administering to a mammal by inhalation a recombinant AAV (rAAV) comprising a transgene encoding apolipoprotein E under control of regulatory sequences which direct expression of the product in lung cells transfected the rAAV, whereby the expressed product is passed to the bloodstream from the lung cells, classifiable in class 514, subclass 44.

II. Claims 1-7 and 10-17 and 19, drawn to a non-invasive method for obtaining pharmaceutically effective levels of a gene product in the bloodstream of a mammal, the method comprising administering to a mammal by inhalation a rAAV comprising a transgene encoding erythropoietin under control of regulatory sequences which direct expression of the product in lung cells transfected the rAAV, whereby the expressed product is passed to the bloodstream from the lung cells, classifiable in class 514, subclass 44.

III. Claims 1-7 and 10-17 and 19, drawn to a non-invasive method for obtaining pharmaceutically effective levels of a gene product in the bloodstream of a mammal, the method comprising administering to a mammal by inhalation a rAAV comprising a transgene encoding Factor IX under control of regulatory

sequences which direct expression of the product in lung cells transfected the rAAV, whereby the expressed product is passed to the bloodstream from the lung cells, classifiable in class 514, subclass 44.

IV. Claims 1-7, drawn to a non-invasive method for obtaining pharmaceutically effective levels of a gene product in the bloodstream of a mammal, the method comprising administering to a mammal by inhalation a rAAV comprising a transgene encoding Factor VIII under control of regulatory sequences which direct expression of the product in lung cells transfected the rAAV, whereby the expressed product is passed to the bloodstream from the lung cells, classifiable in class 514, subclass 44.

V. Claims 1-6, 8-17, and 21-22, drawn to a non-invasive method for obtaining pharmaceutically effective levels of a gene product in the bloodstream of a mammal, the method comprising administering to a mammal by inhalation a rAAV comprising a transgene encoding an antibody or a functional fragment thereof under control of regulatory sequences which direct expression of the product in lung cells transfected the rAAV, whereby the expressed product is passed to the bloodstream from the lung cells, classifiable in class 514, subclass 44.

VI. Claims 10-17 and 20, drawn to a pharmaceutical kit for delivery of a secreted product, said kit comprising: a suspension for aerosol or spray delivery of a predetermined dose by inhalation, said suspension comprising a rAAV

comprising a transgene encoding an insulin protein and a physiologically compatible carrier, classifiable in class 435, subclass 320.1.

VII. Claims 10-17 and 21, drawn to a pharmaceutical kit for delivery of a secreted product, said kit comprising: a suspension for aerosol or spray delivery of a predetermined dose by inhalation, said suspension comprising a rAAV comprising a transgene encoding a synthetic transcription factor that dominantly repressed the presinillin promoter and a physiologically compatible carrier, classifiable in class 435, subclass 320.1.

The inventions are distinct, each from the other because:

Invention I and Inventions II-VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions. The transgene set forth in each group is not disclosed as capable of use together and has a different mode of operation, different function and different effect. For example, a method of delivering a rAAV comprising a transgene encoding an apolipoprotein E is not capable of use together with a method of delivering a rAAV comprising a transgene encoding Factor VIII. In addition, a pharmaceutical kit comprising a rAAV comprising a transgene encoding Factor IX is not disclosed as capable of use together with a kit comprising a rAAV comprising a transgene encoding a synthetic zinc finger transcription factor.

Claim 1 link(s) invention I and Inventions II-V. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 1. Claim 10

link(s) Invention I and Inventions II-III and Invention V-VII. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 10. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

If applicants elect Invention V, applicants are further required to elect a species from the following:

Claims 8 and 22 are generic to a plurality of disclosed patentably distinct species comprising a transgene encoding an antibody listed on page 13, lines 6-15. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

NOTE: If applicants elect an antibody other than the anti-presinillin single chain antibody listed in claims 9 and 21, then claims 9 and 21 will be considered drawn to a non-elected species.

Because these inventions are distinct for the reasons given above and the search required for each Group listed above is not co-extensive for any other Group, restriction for examination purposes as indicated is proper.

It would be unduly burdensome for the examiner to search and consider patentability of all of the presently pending claims, a restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 § 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (703) 305-0775.

The examiner can normally be reached on Monday through Friday from 8:00 to 5:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader, SPE - Art Unit 1635, can be reached at (703) 308-0447.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Brian Whiteman
1635

Scott D. Priebe

SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER